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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,348	01/30/2004	Ramachandran Thembalath	IPCA	6363

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/768,348	THEMBALATH ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 26-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 26-36 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Preliminary Amendment filed 01/30/04, and Petition to Make Special filed 06/20/04.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on applications filed in India on 04/17/03, 09/18/03, and 10/31/03. It is noted, however, that applicant has not filed a certified copy of the foreign priority applications as required by 35 U.S.C. 119(b).

Response to Amendment

The amendment filed 01/30/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added materials which are not supported by the original disclosure is as follows:

The term "approximately" in claims 27, 30, 32, 34 and 36;

Step C in the process for manufacturing a substantially moisture stable pharmaceutical product;

The limitation "pharmaceutical-acceptable coating comprises a gelatin capsule" in claim 29; and

The limitations "[a] substantially moisture stable core comprising a drug substance, ethyl cellulose and surfactant", and "outer layer substantially free of said drug substance".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It appears that applicant's specification does not provide support for the limitations submitted in the Preliminary Amendment dated 01/30/04.

Applicant's specification at page 9 discloses the amount of polysorbate 80 is 2.00 mg and the amount of ethyl cellulose is 0.33 mg, which has a ratio of 1.00:0.165. However, nowhere in the specification disclose "a ratio of approximately 1.00:0.165" in claims 27, 30, 32, 34 and 36.

Example 2 of the specification discloses mixing ethyl cellulose, organic solvent, alcohol and surfactant to obtain a moisture barrier coating solution, loading paroxetine

hydrochloride (HCl), and spraying the coating solution onto the paroxetine HCl, the coated granule was dried, mixed with other excipient, and compressed into tablet, the tablet can be coated with HPMC. However, nowhere in the specification disclose "*polar* solvent", step C, "coating the substantially moisture-resistant drug substance of step B in a pharmaceutically-acceptable coating" in claims 26 and 28, and "wherein said pharmaceutically-acceptable coating comprises a gelatin capsule" in claim 29.

Specification at page 6 discloses ethyl cellulose in the coating solution. Nowhere in the specification disclose the limitations "[a] substantially moisture stable core comprising a drug substance, ethyl cellulose and surfactant", and "outer layer substantially free of said drug substance" in claim 33.

For examining purpose, the claims are interpreted in view of the specification as an active core coated with a moisture barrier coating solution comprising ethyl cellulose, organic solvent, alcohol and surfactant. The coated core can be incorporated into a gelatin capsule.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 is rejected in the use of the phrase "a pharmaceutically acceptable material" in lines 4-5. What is pharmaceutically acceptable material? Applicant's specification does not define or disclose "pharmaceutically acceptable material".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. US 6,270,805.

Chen discloses a controlled release formulation for water-soluble drugs comprising active core, and a delayed or enteric coating over the core (see abstract, column 3, lines 11-24, and column 4, lines 1-45). Water-soluble drugs include paroxetine hydrochloride (column 3, lines 3-10). The core comprises water-soluble drug, ethyl cellulose, and surfactant (column 5, lines 30 through column 6, lines 1-20).

Claims 26, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Buxton et al. US 5,601,845.

Buxton discloses a coating composition comprising ethyl cellulose, polysorbate 80 as a surfactant, plasticizer, and mixture of solvent selected from dichloromethane, ethanol, methanol, acetone, and isopropyl alcohol (see abstract, column 2, lines 31-67, and column 3, lines 3-9). Buxton also discloses the process comprising mixing the ingredients of the coating composition, applying the coating to a drug spheroid core, the coated spheroid is filled into gelatin capsule (column 4, lines 1-25).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 26-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buxton et al., in view of Chen et al.

Buxton is relied upon for the reason stated above. Buxton does not expressly teach the claimed active agent.

Chen teaches a controlled release formulation for water-soluble drugs include diltiazem, and paroxetine hydrochloride (column 3, lines 3-10). Thus, it would have been obvious for one of ordinary skill in the art to modify the spheroid formulation of Buxton using paroxetine in view of the teaching of Chen, because Chen teaches the similarity of water-soluble drugs including diltiazem and paroxetine (column 3, lines 3-9), and because Buxton teaches a controlled release formulation for diltiazem.

The cited references do not teach the claimed ratio between polysorbate 80 and ethyl cellulose. However, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine suitable amounts of polysorbate 80 and ethyl cellulose to obtain the claimed invention, because Buxton teaches the use of ethyl cellulose as a suitable coating polymer and polysorbate 80 as a suitable surfactant in a controlled release formulation, and Chen teaches the use of ethyl cellulose as a coating polymer useful to control the release rate of water-soluble drug.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Elder et al., Cohen et al., Felumb et al., and Chickering, III et al. are cited as of interest for the teachings of stable paroxetine formulations. Seminoff et al. and Porter et al. are cited as of interest for the teaching of coating compositions.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Tran
Patent Examiner
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